

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
MDL 2545

IN RE	§	
	§	
TESTOSTERONE REPLACEMENT	§	Case No. 1:14-cv-01748
THERAPY PRODUCTS LIABILITY	§	
LITIGATION	§	

**LARRY LIPSHULTZ, MD'S OBJECTIONS AND RESPONSES TO SUBPOENA**

Pursuant to Federal Rule of Civil Procedure 45(d)(2)(B), Nonparty/respondent Larry Lipshultz, MD files these Objections and Responses to the subpoena issued to him in the above-numbered and -referenced cause.

Respectfully submitted,

KROGER | BURRUS

BY: 

E. Dale Burrus

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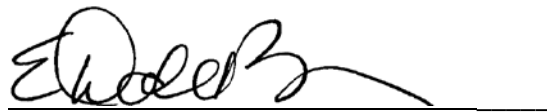
ATTORNEY FOR  
LARRY LIPSHULTZ, MD

**CERTIFICATE OF SERVICE**

The foregoing document was served in compliance with the Federal Rules of Civil Procedure by the methods designated below, or if not designated, by United States Postal Service First Class Mail, on this, the 23rd day of March 2017.

Todd E. Hilton  
STUEVE SIEGEL HANSON  
460 Nichols Road, Suite 200  
Kansas City, Missouri 64112

☐ via certified mail/return receipt requested  
☒ via facsimile (816) 714-7101  
☐ via hand delivery  
☒ via email: hilton@stuevesiegel.com

A handwritten signature in black ink, appearing to read "E. Dale Burrus", is written over a horizontal line.

E. Dale Burrus

**DOCUMENTS TO BE PRODUCED**

1. A copy of your full, complete, and current curriculum vitae.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore exceeding the bounds of fair discovery. This request demands the production of information and documentation that is neither necessary nor relevant to issues underpinning the litigation at hand, particularly to the extent that it seeks Dr. Lipshultz's personal documents and information. Further, responsive information is available to Plaintiffs within the public domain, as well as from parties to this suit. The information requested in no way relates to the issues in this matter, and, as such, the request serves as nothing more than harassment and an unwarranted fishing expedition.

2. Any and all documents, memoranda, agreements, communications, memorializations, letters, grant proposals, contracts, and proposals prepared by any individual or entity (including yourself or Auxilium) and whether or not exchanged between you and Auxilium, which relate to, pertain to, or otherwise discuss or describe any and all professional services rendered by you, or proposed to be rendered by you, to Auxilium relating to testosterone products including but not limited to those marketed and sold by Auxilium.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and

documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs' specifications is substantial in terms of both expense and inconvenience, particularly when responsive information is more readily available through the public domain and parties to the lawsuit.

3. Any and all documents, memoranda, agreements, communications, memorializations, presentations, slides, slide decks, manuscripts, monographs, white papers, video or audio recordings, letters, grant proposals, contracts, and proposals prepared by any individual or entity (including yourself or Auxilium), whether or not exchanged between you and Auxilium, which relate to, pertain to, or otherwise discuss or describe any and all professional services rendered by you, or proposed to be rendered by you, to, for, or on behalf of Auxilium with respect to:

- a. The education and training of Auxilium personnel, including employees, officers, directors, agents, vendors and contractors, regarding, relating to, or otherwise pertaining to testosterone, hypogonadism, testosterone deficiency, the indications and use for testosterone therapy, the complications and adverse events associated with or caused by testosterone administration to men, and the hypothalamic-pituitary-testicular axis and its regulation;
- b. The provision of services as Key Opinion Leader (KOL), or Opinion and Thought Leader (OTL), member Auxilium's Speakers Bureau, or educator of healthcare providers performed for or on behalf of Auxilium regarding, relating to, or otherwise pertaining to testosterone, hypogonadism, testosterone deficiency, the indications and use for testosterone therapy, the complications and adverse events associated with or caused by testosterone administration to men, and the hypothalamic-pituitary-testicular axis and its regulation;
- c. Any and all work as a consultant, or in the provision of consulting or consultative services, for, or on behalf of, Auxilium regarding, relating to, or otherwise pertaining to testosterone, hypogonadism, testosterone deficiency, the indications and use for testosterone therapy, the complications and adverse events associated with or caused by testosterone administration to men, and the hypothalamic-pituitary-testicular axis and its regulation;
- d. The provision or proposed provision of any and all Investigator Initiated Studies or Investigator Initiated Trials for, on behalf or, or with support from Auxilium in which you were or were proposed to be an investigator or consultant;

- e. The submission for and publications of any articles, journals, entries, reports, analysis, opinion pieces, papers, abstracts, or other works, for, at the request of, with, or on behalf of Auxilium;
- f. The provision of or participation in Continuing Medical Education (CME) programs, conferences, and presentation on topics or subjects regarding, relating to, or otherwise pertaining to testosterone, hypogonadism, testosterone deficiency, the indications and use for testosterone therapy, the complications and adverse events associated with or caused by testosterone administration to men, and the hypothalamic-pituitary-testicular axis and its regulation which were funded in whole or in part by Auxilium;
- g. The preparation or presentation of any speeches, talks, presentations, discussion, educational materials at a medical professional society or profession medical organization conference or meeting on topics or subjects regarding, relating to, or otherwise pertaining to testosterone, hypogonadism, testosterone deficiency, the indications and use for testosterone therapy, the complications and adverse events associated with or caused by testosterone administration to men, and the hypothalamic-pituitary-testicular axis and its regulation which were funded in whole or in part by Auxilium or which were performed for or on behalf of Auxilium;
- h. Services provided to or as a member of any Advisory Board, Scientific Advisory Board, advisory committee, advisory conference, scientific meeting, or scientific or marketing meeting within, for, or on behalf of Auxilium on topics or subjects

regarding, relating to, or otherwise pertaining to testosterone, hypogonadism, testosterone deficiency, the indications and use for testosterone therapy, the complications and adverse events associated with or caused by testosterone administration to men, and the hypothalamic-pituitary-testicular axis and its regulation;

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs' specifications is substantial in terms of both expense and inconvenience, particularly when responsive information is

more readily available through the public domain and parties to the lawsuit.

4. All documents, memoranda, agreements, communications – both written and electronic, notes, memorializations, and contracts relating or referring to the *Testosterone in Older Men with Mobility Limitations* conducted by S. Bhasin, MD (“TOM Study”) which was stopped in December 2009, and the subsequent Basaria, S., et al., *Adverse Events Associated with Testosterone Administration*, NEJM, July 8, 2010.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs’ specifications is substantial in terms of both



expense and inconvenience, particularly when responsive information is more readily available through the public domain and parties to the lawsuit.

5. All documents, memoranda, agreements, communications – both written and electronic, notes, memorializations, white papers, drafts, or outlines relating to your participation in Auxilium’s response to the TOM Study, including without limitation, the Advisory Board meeting held in response of which you were a part, and the FaCTT Initiative: Frail population and CV Risk with Testim Treatment, as well as any other consulting, writing, speaking, presenting, advising, participating, meeting, or communication you did with or for Auxilium, its employees, officers, directors, agents, representatives, or contractors.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on

Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs' specifications is substantial in terms of both expense and inconvenience, particularly when responsive information is more readily available through the public domain and parties to the lawsuit.

6. All documents, memoranda, agreements, communications – both written and electronic, notes, memorializations, and contracts with Auxilium relating or referring to other tests or studies relating to TRT products, including, without limitation, Vigen, R. et al., *Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels*, JAMA, Nov 13, 2013; and Finkle, W.D., et al., *Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men*, PLOS ONE, Jan. 29, 2014.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and

an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs' specifications is substantial in terms of both expense and inconvenience, particularly when responsive information is more readily available through the public domain and parties to the lawsuit.

7. All documents, memoranda, agreements, communications – both written and electronic, notes, presentations, outlines, drafts, and contracts between you and any agent, employee or consultant for Auxilium (or any of its affiliates, agents or representatives), relating to any participation or presentation at any professional conference or meetings at the request of, instruction by, or on behalf of Auxilium, including without limitation, The Endocrine Society or American Urological Association.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range

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8. Any and all correspondence, discussions, information exchanges, documents, and materials with the Publication Steering Committee at Auxilium regarding planned, proposed, written, outlined, or described publications on the topic of testosterone or testosterone therapy.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range

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9. All documents relating to any Auxilium Advisory Board or Advisory Committee at Auxilium of which you were a member or sat upon, including without limitation, meeting minutes, presentations, memoranda, communications – both written and electronic, outlines, talking points, videos, contracts, and agreements.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range

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10. All documents relating to any Auxilium committee or board which included Auxilium personnel, officers, directors, employees or agents, of which you were a member or participant, including without limitation, meeting minutes, presentations, talking points, outlines, attendance lists, memoranda, communications – both written and electronic, contracts and agreements.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient

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11. All documents and recordings relating to any video or digital recording on which you appear at the request of, on behalf of, in furtherance of, in conjunction with, or for Auxilium, including without limitation, DVD, other digital media, outlines, scripts, transcripts, talking points, drafts, exhibits, memoranda, communications – both written and electronic, presentations, interviews, feedback and contracts.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues

underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs' specifications is substantial in terms of both expense and inconvenience, particularly when responsive information is more readily available through the public domain and parties to the lawsuit.

12. Any and all documents, memoranda, agreements, communications, notes, memorializations, and contracts between you and any agent, employee or consultant for Auxilium (or any of its affiliates, agents or representatives), including but not limited to documents relating to the potential risks, benefits, guidelines and/or indications for Auxilium's TRT products.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and



documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and an unwarranted fishing expedition. To the extent that relevant and responsive information exists, it is equally available to Plaintiffs through both the public domain and through parties to the lawsuit. The burden on Dr. Lipshultz, a nonparty, to examine extensive records and documents and to then produce documents responsive to this nonexclusive request in accordance with Plaintiffs' specifications is substantial in terms of both expense and inconvenience, particularly when responsive information is more readily available through the public domain and parties to the lawsuit.

13. Any and all documents, memoranda, agreements, communications, notes, memorializations, and contracts with any federal or state regulatory agencies, including but not limited to the United States Food and Drug Administration and the National Institutes of Health referring or relating to Auxilium's TRT products.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and

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14. Any and all meeting minutes or other documents that purport to memorialize the conduct or substance of any meeting which refers or relates to Auxilium's TRT products, including potential risks and potential benefits.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues

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15. Any and all documents identifying the attendees of any meetings referring or relating to TRT products.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range

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16. Any and all documents, memoranda, agreements, communications, notes, memorializations, and contracts between you and any media entity referring or relating to Auxilium, or its TRT products.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to

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17. Any and all documents, memoranda, agreements, communications, notes, memorializations, and contracts referring or relating to any advertisement, promotion, sales, or marketing for Auxilium's TRT products.

**RESPONSE:** Dr. Lipshultz objects to this request on the grounds that it is overbroad on its face and poses an undue burden on a nonparty, therefore far exceeding the bounds of fair discovery. This request makes an all-encompassing demand for the production of information and documentation that is neither necessary nor relevant to the issues underpinning the litigation at hand, and does so without sufficient specificity or limitation of scope. Further, this request seeks a broad range of personal documentation that in no way relates to the issues central to this matter, and, as such, constitutes nothing more than harassment and

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